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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,853	09/12/2003	Stephen D. Pacetti	50623.331	2165

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EXAMINER	
SELLMAN, CACHET I	

ART UNIT	PAPER NUMBER
1792	

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10/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/660,853	PACETTI ET AL.	
	Examiner	Art Unit	
	Cachet I. Sellman	1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-23,25-50 and 52-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,20-23,25-42,44,45,49-53,55-58,64-66 and 70-80* is/are rejected.

7)☒ Claim(s) *19,43,46 and 54, 59-63, 67-69* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

This action is being mailed in response to the telephone interview with applicant in regards to the finality of the previous office action dated 8/8/2007. The Examiner agreed that the Office Action mailed 8/8/2007 should have been a Non-Final Action therefore this supplemental Action is being mailed to withdraw the finality. Acknowledgement is made of the amendment filed by the applicant on 5/29/2007, in which claim 17 was cancelled and claims 18-23, 27-29, 34, 59, 64, and 70 were amended. Claims 17-23, 25-50, and 52-80 are currently pending in U.S. Application Serial No. 10/660,853.

Claim Objections

1. Claim 70 is objected to because of the following informalities: The word –end— should be added after "second" in line 4. Appropriate correction is required.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 27-28, 64-65, and 70-72 are rejected under 35 U.S.C. 102(e) as being anticipated by Parson et al. (US 6521284).

Parson et al. discloses a process for coating an implantable medical device such as a stent (col. 9, lines 11-13, and 6 of Fig. 1), where the stent is positioned on a mounting assembly (see Fig. 1) where the mounting assembly includes a porous surface. The medical device is mounted on a mandrel (2 of Figure 1) having two spacers (4a and 4b) located at the ends of the medical device (6); the mandrel has pores (12 of Fig. 2 and col. 2,lines 60-65). A coating material is applied to the stent and the pores are configured to receive some of the coating due to overflow (col. 4, lines 63-67) as required by **claims 27 and 64**. The mandrel (2) extends from the first member (4a) to the second member (4b) connecting the two members as required by **claim 25**. The mandrel is spaced to not make contact with the stent as required by **claims 26 and 65**. The pores are interconnected on the surface of the mandrel therefore providing an open pore system (Fig. 2) as required by **claim 28**.

The support system comprises of a material that are porous such as sintered metal, ceramic, and polymeric materials (col. 5, lines 12-14) which would inherently absorb some of the coating material as required by **claim 29**. Parsons et al. further teaches a coating composition including a solvent and a polymeric material (col. 6, lines 27-29) as required by **claims 30 and 66**.

Parson et al. discloses positioning a stent on a mounting assembly (Fig. 1) which comprises a first member to support a first end (4a), a second member to support a

second end (4b) and a third member extending through the sent and connecting the first and second members (2); and applying a coating composition to the stent where the third member (mandrel) is made of an absorbing material that absorbs some of the coating composition during the application as required by **claim 70**. The third member is spaced away from the inner surface of the stent as required by **claim 71**. Parsons et al. further teaches a coating composition including a solvent and a polymeric material (col. 6, lines 27-29) as required by **claim 72**.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 31-32 and 73-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parson et al. as applied to claims 29 above in further view of Hossainy et al. (US 6153252).

The teachings of Parson et al. as applied to claim 29 are as stated above. Parson et al. does not teach rotating the stent about a longitudinal axis as required by **claims 31 and73** .

However, Villareal teaches a stent mounting device used in a process for coating the stent where the stent is mounted on a mandrel and supported on the ends by the coning ends. The stent is coated with a polymer dissolved in a solvent with an active agent and is rotated aver coating in order to remove the solvent from the stent to form a coating having a desired thickness without coating defects.

It would have been obvious to one having ordinary skill in the art to modify the process of Parson et al. to include rotating the stent after coating as taught by Villareal in order to remove the solvent as well as provide a coating having a desired thickness and without any defects.

Villareal teaches moving the stent in a linear direction along a longitudinal axis (col. 3, lines 11-19) as required by **claims 32 and 74**.

6. Claims 18, 20-23, 25-26, 29-42, 44-45, 49-53, 55-58 and 76-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (US 2003/0215564) in view of Jendersee et al. (US 5836965), Helfrich (US 5308338) and Scanlon et al. (US 2845346).

Heller et al. ('564) teach several methods for coating stent (Abstract). In one embodiment, Heller et al. ('564) teach using a catheter as the mandrel or work support when coat the stent (page 6, [0086]). The mounting assembly of Heller et al. ('564) comprises a hollow tubular catheter having a central lumen and an inflatable balloon (page 2, [0025]) tip, i.e. first member and second member of the mounting assembly. The sent is mounted on the balloon tip (see fig. 7), i.e. the first end of stent is in contact with first member and second end of the stent is in contact with second member. Heller et al. ('564) do not specifically teach the porous surface of the catheter balloon tip. However, Heller et al. (page 4, [0048]) teach the catheter is a substantially tubular and generally flexible device that carried fluids into or out of the body.

Heller et al. does not teach that the first and second members are porous as required by **claim 18, 29, 34, 39, 53 and 76**.

Jendersee et al. teaches a mounting device for supporting a stent where the device comprises a tubular support member (36) for supporting the stent, a first member (retainer 54) contacting a first end of the stent, a second member (retainer 54) contacting a second end of the stent where the retaining elements can be made form any implantable material such as stainless steel or polymers (col. 7, lines 34-54). Jendersee et al. does not teach that the retaining elements have porosity.

However it was known in the art at the time the invention was made to provide a catheter with cuffs made from porous implantable materials from polymers to sintered metal and ceramics as taught by Helfrich (see col. 4, lines 31-39).

Scanlon et al. teaches enabling sintered metal bodies to be made of a closed pore construction (col. 1, lines 15-23).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the process of Jendersee et al. to make the retainers of any appropriate porous and /or non-porous implantable material so as to retain the stent on the catheter as well as to enable the catheter with the stent to be used in or out of the body. As taught by Helfrich one would have made the retainers of a porous material in order to enable absorption or retention of fluid when the stent is pretreated or enable tissue growth when the device is implanted.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the process of Heller et al. to include the assembly of Jendersee et al. One would have been motivated to do so because both discloses using catheters to deliver stents and Jendersee et al. further teaches that the device provides stability, and does not require a sheath which substantially decreases the cross sectional profile of the balloon delivery device.

The stent of the teaching of Heller et al. ('564) is rotating about a longitude axis of the stent (page 6, [0086]) and moving about a longitude axis of the stent (see Fig.2) as required by **claims 21-22, 31-32, 36-37, 56-57, 78-79 and 50-51**. The coating solutions of the teaching of Heller et al. ('564) consist of polymer and solvent (page 5, [0073] and [0074]) as required by **claims 20, 30, 35, 55 and 49.**The coating solution is applied onto the stent by spraying (page 6, [0081]) as required by **claims 23, 33, 38, 58, 77, 80 and 52**.

Heller et al. ('564) teach that both end of stent are affixed to the rotatable spool via a wire which is threaded through the length of the catheter's central lumen, i.e. the third member of the mounting assembly, and emerges from a hole in the catheter's two ends, thus the said wire, i.e. the third member, is not in contact with the stent as required by **claims 25-26**.

As stated above the retainers can be made of stainless steel as required by **claims 40-41** or a polymeric material as required by **claim 42**. The members can be ceramic material as required by **claim 44**.

Allowable Subject Matter

7. Claims19, 43, 46-47, 54, 59-63, and 67-69 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cachet I. Sellman whose telephone number is 571-272-0691. The examiner can normally be reached on Monday through Friday, 7:00 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cachet I Sellman
Examiner
Art Unit 1792

cis

/William Phillip Fletcher III/
Primary Examiner